

## THE WALTER REED ARMY INSTITUTE OF RESEARCH

# *Malaria and Leishmaniasis Drug Development*

### ***Mission***

To prevent and minimize the morbidity and mortality caused by malaria and cutaneous leishmaniasis in military personnel by the development of novel drugs for prevention and treatment in currently available drugs.

### ***Major Accomplishments***

- Completed a 13 year development and testing effort for a point of care malaria diagnostic test with a commercial partner with final FDA approval in July 2007.
- Completed a 4 year development effort to improve the diagnosis of CL with a July 2010 submission of a molecular diagnostic test to the US FDA.
- Advanced development of rapid diagnostic dipstick tests and skin test for CL.
- Historically, the WRAIR has filed over 60 INDS, developed or co-developed all of the FDA approved and currently used anti-malarial in the USA.

### ***Did you know...***

- WRAIR is the only institution in the world focused on developing new drugs for the prevention of malaria in healthy adults and
- WRAIR is the only institution in the world equipped with a dedicated cutaneous leishmaniasis drug development program.
- Malaria is the most important tropical infectious disease threat to military populations, especially in sub-Saharan Africa. All currently available anti-malarial drugs are either poorly tolerated or their future is threatened by emerging drug resistance.
- Cutaneous Leishmaniasis (CL) is the most neglected of the Neglected Tropical Diseases (NTDs). The World Health Organization estimates over 2 million new cases per year. CL is a persistent threat to deployed military forces primarily diagnosed from Iraq and Afghanistan. Since 2003, over 3,5000 parasitological cases have confirmed as CL. Currently, there are no vaccines, no prophylaxis, or FDA approved drug treatments from CL.

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### *Malaria Vaccine Program*

#### ***Mission***

To develop both *P. falciparum* and *P. vivax* malaria vaccines that prevent malaria morbidity and mortality in military personnel and in vulnerable populations for the benefit of global public health. USMMVP is the world's foremost malaria vaccine development program, integrating a broad translational enterprise encompassing basic research and discovery; pre-clinical research and development, vaccine production, clinical research, and field trials through the world from laboratory bench to clinical trials center to field studies.

#### ***Major Accomplishments***

- In 2009 and 2010, USMMVP conducted the first human clinical trials of the *P. vivax* malaria challenge in naïve subjects. This resulted in the demonstration of its safety and reproducibility. The human subject challenge model is crucial to test new vaccines and drugs against both strands of malaria
- In 2010, the WRAIR initiated the very first live genetically-attenuated malaria sporozoite vaccine in humans in a phase 1/2a trial in collaboration with Seattle Biomed and the Walter & Eliza Hall Institute

#### ***Did you know...***

- Malaria is a global problem with approximately 1.5 million deaths per year caused by *P. falciparum* and *P. vivax* malaria and one half billion persons at risk of infection.
- The malaria threat is worldwide and has resulted in large numbers of casualties in US and Allied Forces in deployments to Southeast Asia, the Pacific, Middle East, and Africa. Sub-Saharan Africa poses the greatest risk due to the intensity of transmission.

To learn more, visit us on the web: [wrair-www.army.mil](http://wrair-www.army.mil)

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